

# **Clinical Operations Workgroup Draft Transcript February 19, 2010**

## **Presentation**

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Good morning and welcome, everybody, to the HIT Standards Committee Clinical Operations Workgroup. Just a reminder that the public is on the call and there will be opportunity at the close of the call for the public to make comments and, workgroup members, if you could please remember to identify yourselves when speaking.

Let me do a quick roll call. Jamie Ferguson?

### **Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Present.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

John Halamka?

### **John Halamka – Harvard Medical School – Chief Information Officer**

Present.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Christopher Chute? Martin Harris? Stan Huff? Kevin Hutchinson or David Kates? Liz Johnson? John Klimek

### **John Klimek – NCPDP – VP Industry Information Technology**

Present.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Wes Rishel?

### **Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Here.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Nancy Orvis? Karen Trudel? Chris Brancato.

### **Chris Brancato – Deloitte – Manager, Health Information Technology**

Here.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Don Bechtel? Joyce Sensmeier? Lisa Carnahan? Eric Strom?

### **Eric Strom – DoD Military Health System – Program Management Support**

Here.

### **Judy Sparrow – Office of the National Coordinator – Executive Director**

Did I leave anybody off? Okay, with that I'll turn it over to Jamie Ferguson.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay. Judy, thank you very much. We only have one agenda item for this call and if we take the full two hours that's great; if we don't that's also great. What we wanted to do was to gather additional input on our comments for discussion with the full Standards Committee next week regarding comment letters that the Standards Committee will prepare on the EHR interim final rule, as well as the meaningful use NPRM. What I'd like to do; and please excuse my voice is a little rough; but what I'd like to do first is just read through and review the discussion notes that I have from our previous discussion that I've captured in PowerPoint bullets that are just in draft form, which is why I didn't put them out yet. I also have my text notes from our previous comments. I will be formatting these for submission to the Standards Committee for next week. Let me first just read through what we've talked about so far and then see if folks want to change that or see what additions might be needed.

Our discussion sort of jumped around a bit and what I've done is I've categorized it into buckets. The first bucket is areas where we found that more specific guidance is needed and where we wanted to recommend to the Standards Committee that ONC should issue a guidance letter or letters as soon as possible, immediately to add constraints to eliminate optionality. One of the primary examples of that was in the repeated use of HL7 2.5.1 for content exchange messaging and basically in all the places where 2.5.1 is mentioned we wanted to recommend specific guidance for implementation. It should be recommended immediately.

Then there are similar needs that we talked about for vocabularies in terms of implementation guidance for vocabularies for laboratories, medications, vaccinations, problems and procedures in particular.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Jamie, were you thinking about things like ... subsets in that guidance or just ...?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, I mean at this point it's just generally an area where we've pointed out a need for specific guidance. I have actually a different sort of bucket for the vocabulary comments, so if you could hold that thought for a few minutes –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Okay. Sure.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I think, yes, we did talk about the need for specific subsets; the value sets for the adopted vocabularies. Then the last area where we talked about specific guidance being needed was in the particular C32 implementation guide for CCD that we thought would be helpful. So what I'm going to suggest is let me just read through all the different buckets first and then perhaps we can go back and talk a little bit about each one.

The second bucket had to do with interoperability and what's required essentially for interfaces or interoperability versus what's required inside the EHR. In general, we wanted to request verification on what's required inside the EHR versus what's required only for interoperability ... and we talked about that in terms of problems and labs potentially being in the EHR, medications being only for interoperability, but then we didn't have consensus on that. Other folks felt that ... SNOMED and RxNorm should be required only for interoperability. There was a question about whether immunizations ... needed to be captured inside the EHR or for interoperability only.

Then that actually led us into a related discussion about where we used SNOMED I think as an example and not limited to SNOMED, but we said that while the specified or adopted vocabulary should be required for interoperability, anything that is a perfect match could be used inside .... That actually led us into a discussion about the fact that mapping is always imprecise and the only thing that's truly a perfect match would be adopted vocabulary itself. But, again, we didn't come to a consensus on that. This was a point that we wanted to ... the Standards Committee. Then, finally, in this bucket we wanted to recommend that specific minimal vocabulary subsets should be requirements for interfaces that should be part of the certification process so that there would be at least a minimum set not a comprehensive set of the adopted vocabularies, but a minimal set that would be required for interoperability that could be part of ... process.

The next bucket of discussion items had to do with CCD versus CCR. We had two or three subjects of discussion in this bucket. One is that it wasn't clear how to use CCR as a source of data for quality reporting. So we had a discussion about that and that led us to think of these two different documents as being really for different purposes and so one of the things that we wanted to raise with the Standards Committee was the possibility of perhaps restricting the use of the different documents to different purposes. Again, this is a suggestion, not a consensus recommendation, so that's an item that we wanted to bring up for discussion just based on the fact that these really are different documents that are intended for different purposes.

The last thing in this bucket was about DEA level two versus level three and the point that was brought up there is that level two implies no machine ... and so there's a question about whether that means we have to put the coded entries into the ... section ... to make sense. Then it was also noted that the adoption of DEA only in level two is inconsistent with the Notice of Proposed Rule Making for ..., which we also had supported in the Standards Committee. We wanted to note that inconsistency and hope for adoption of level three as well as level two.

The next bucket are just a couple of points that we talked about in terms of inconsistency between the interim final rule and the NPRM. There are a couple of things that are required in the interim final rule we've noted, but that are not used in the NPRM. So we didn't come to consensus on whether the things that are required in the IFR should be required to be used or whether they should potentially be dropped. But that was the general ... of the discussion and that has to do with for example ... core operating rules, our requirement for EHR, but they're not used in the NPRM, only in HIPAA transactions ... required. Similarly, the requirements for EHRs to be capable of CCD and CCR isn't used in the places where it might be used in the NPRM.

The next bucket are a couple of items that we noted that were inconsistencies with HIPAA. In the IFR, the CAQH core phase one rules are required for both, the 40-10 series of administrative transactions, as well as the 50-10 series. The core phase one exists only for X12 40-10 A1 and yet it's required for use with the 50-10, which doesn't actually make sense. So we wanted to request that that be clarified in the final rule.

Another thing that has come up is that it appears the definition of ... in the IFR using the ... may be inconsistent with the definition ... encryption that's used in HIPAA guidance that was issued recently for ... notification. So we referred that over to Dixie for her workgroup ... to really fit in our workgroup ....

The final bucket is what Wes had brought up earlier, the vocabulary comment. There we wanted to recommend a series of needs that should be met quickly for .... One is to have frequency ... starter sets. These are, for example, most commonly ... for the quarter .... So the frequency starter sets are ... for the adopted vocabulary. Another one is specialty subsets. These are not in priority order, but these are just

the different needs that we talked about. The second one would be specialty subsets for a particular medical specialty to use.

The third area, there are two areas in terms of value sets where starter sets or subsets are convenience for implementers, but not comprehensive for any particular purpose and so with value sets, in contrast, define essentially the universe of codes or context for a particular purpose. And so the quality value sets are the primary example of value sets that need to be determined, disseminated, maintained and so forth, but that need to get out to the hands of implementers quickly in order to enable essentially .... There may be other value sets. We didn't really – or maybe my notes are incomplete – but I didn't capture notes on other value set requirements in that conversation.

Then two other things in terms of vocabularies: One is to recommend that there is a need for coordinating releases of the adopted vocabularies so that we don't have changes. If you have a terminology service or service provider that encompasses multiple or all of the adopted vocabularies as an example or anything more than one ... have to go in and touch that subsystem constantly for uncoordinated releases. So we wanted to recommend that there should be coordination of the releases for updates and maintenance of the vocabularies themselves, as well as the subsets and value sets.

Then finally and this ... the vocabulary bucket back to the interoperability bucket, we wanted to recommend that there should be a minimum floor of vocabulary requirements for interoperability in certification of EHRs so that there would have to be some minimal set. And this could be one of the frequency based starter sets or something different, but that some minimal floor for interface purposes should be part of the certification process.

So those are all of the buckets that I captured our comments into. I'll just walk through them; go back in the same order and ask for questions, comments –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst** Jamie, before you do that can we have a general talk about ... several of the buckets?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**  
Sure. Please.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst** I'm going to start out by stating my interpretation of the two ... at a general level and any time you interpret ... at a general level you start out in trouble, but fundamentally I see the IFR as stating the requirements for how to interoperate and the NPRM has ... requirements to interoperate. Not stating, but not explicitly, but purposefully not stating how. So, for example, if a number of practices are able to get to 50% of their lab data through non-standard interfaces that they've had running for some time, they get credit for importing structured lab data, even though they haven't used the particular interfaces that their EHRs were certified to use. Do we, as a group, have any disagreement with that approach? Because I think it does come up in some of the issues you've described for the buckets.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**  
Yes. No. I mean personally I agree with that approach, but let's hear from others.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst** Whoever disagreed must have been on mute.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes.

**M**

Well, Jamie, just to start some comments that in my conversations with ONC, the reluctance to provide more specific guidance is twofold. One, they're worried the guidance changes so frequently that putting anything in the reg, including, "Oh here is guidance today, but guidance will change and the reg, well, it's temporary," doesn't work very well with reg. That is, it's better to say the reg is general and then there are guidance letters that are issued frequently as guidance changes. So I think part of the presentation has to include, "Well, actually, guidance doesn't change very often." And, that putting 2.5.1 and pointing to a well known implementation guide of 2.3.1 or 2.5.1 or whatever you think appropriate and illustrating that it doesn't change but every couple of years would be important.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes. Okay.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I would like to discuss that point if it's okay, Jamie.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Please.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. So we know through the great ... 50-10 with HIPAA that the regulatory process is quite cumbersome and to a certain extent depends on whether the topic is hot this year or not. That is right now we know that we have tremendous support all the way up to the office of the president for these regulations. A few years from now, we may be running on autopilot and be subject to the kind of prioritization that caused delays in producing HIPAA regulations. So I am not sure whether I would recommend that the regulation include guidance or that the guidance letters be available at the same time or just immediately when it hits the IFR it is final; that the guidance be available soon, I guess would be the best way to say it.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Wes, let me just ask you on that point, so it sounds like you're recommending that the guidance might not be useful or it might not be best to have the guidance available basically at the same time as the final rule

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**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

No. I am recommending that. What I am not recommending is the way I interpreted John's comment, which was to incorporate guidance in the regulation. Again, if we have the same level of attention and staffing at ONC two years from now that we do now and whoever is the president at that time has the same interest in this it's probably not much of a deal, but having lived through HIPAA and lived through the fact that the administrations that implemented it weren't the ones that originally got it from Congress, I

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**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Actually, Wes, your comment I think is right on the mark, but it brings out something that I'd like to air as a possibility for us to discuss with the Standards Committee and that is, and it gets back to John's comment that implementation guidance does not actually change that frequently. In fact, in many cases the standards change more frequently and so, for example, you have HL7 2006 and now working on 2007 for ONC that have come up since the 2.5.1 Lab Implementation Guide actually was ... and has not changed. So I wonder, Wes, if it might make more sense for the reg to designate standards at the level of HL7 v2 or

HL7 v3 and let the guidance be the particular base standard within that family, as well as implementation guidance.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Well, yes. I think that's an interesting point and I'm having trouble fully thinking of all of the ins and outs of it. The plus is that it designates the SDO sort of as a long-term strategy. It takes a new regulation to change the SDO, but it doesn't lock the version in at the level of the standard.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Right. I think that this also goes back to John's point that actually as the implementation guidance may change less frequently than the versions in terms of a particular guide for a particular version.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Which makes you wonder what the hell they're doing with all of those versions, but yes. So I think that a specific proposal for a fairly generic representation in the regulations supported by advice letters is important. I don't want to create the implication that we think that the advice letters will come out frequently in the long-term. I think there's a conservatism about changing interfaces that's good. I do think that we may find during the first two years of putting this into practice that there's a need for more frequent advice letters than later on. I think that was one of the problems with HIPAA was that there was no— if they had been attempted seriously, maybe ... interoperable, which there wasn't, we wouldn't have been able to get changes through the mechanism fast enough.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

And another related issue is that ... they said, "Well, the reason we were reluctant to provide specific implementation guides is because many of these implementation guides are not widely used and so yes, maybe wonderful ... people put them together and they all seem good and right and reasonable. But, show me where they're actually in full production and hence, I'm reluctant to impose something on an industry that hasn't already widely adopted it."

I said, "Yes." I think the question there is to think about the domain. In e-prescribing I think we all agree that the way that we've implemented ... 8.1 and a kind of ... approach using HTP post ... transactions ... is done 100 million times a year by Surescripts. And lab, I guess the way to think about it is HL7 2.3.1 guidance has been available quite a long time and 2.5.1 is really polish on 2.3.1 and so although 2.5.1 may be relatively novel and if we look at the timeline that we have for CDC implementing their public health recording and their immunization 2.5.1 implementation guide we're basically looking at now, you know. They'll be ready in the next 30 days. Okay. It's new, but it's really not a stretch, so I guess I mean how do we overcome the argument of, "Oh, this has not been widely implemented and therefore, standards aren't made, they're adopted."

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

There is also a circular thing there. If you are really standardizing, it's hard to have a new standard become adopted widely without it having been adopted.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy** Right. Exactly. Or on the other side, if the standard had already been universally adopted then no reg would we need it.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I think there's an argument that says specifically there needs to be two ... to mandate an adoption, okay? One is for ... corrections or polishing to existing specifications. The other is for whole new subject areas. For whole new subject areas or major changes in standards approach for an existing subject ... then they

ought to be, as long as they maintain this distinction between what you must do in the NPRM in the final rule and how you get certified for it then it's reasonable to say we can change the certification requirement in a given year but still not expect it to be adopted all in that year ... the time for rollouts and so forth. ... around there, but I think fundamentally we need to make that distinction.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I like that. At the same time it gives an easier path for potential upgrades, but I would be concerned that the adopted standards in the current IFR don't actually perhaps allow that by locking this into 2.5.1 and 2.3.1 as examples. And so I actually had not contemplated it before this discussion, but I wonder if we do want to bring up options ... committee the possibility of making a recommendation for particular examples, HL7 v2, HL7 v3 and ... scripts with no more specificity than that in the regulation with advice letters and guidance and certification providing the needed specificity within those broader constructs.

One thing that comes to mind as a potential benefit of that kind of loosening is eventually it would provide us with a better upgrade path or the possibility for a better planned upgrade path to newer versions of the clinical document architecture, as well as HL7 messaging.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Let me just, in talking about these domains, NCPDP script .... I would argue HL7 v2.x is not really very controversial. I think you could probably find a critical mass of people in the industry with support implementation guidance for the ... level. Now, when you start getting into things like IHE profiles that's where we get into controversy.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

That would be in the advice letters and the certification process and not in the standards that we would recommend adopting, right?

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right. This is where when unfortunately, just thinking about the meeting, some people lump together HL7 implementation guides and IHE profiles. Those are all things that are created by committees that aren't used ..., right? And so, to be clear let's go through ... examples and domains. Let's think about what's truly deployed and what is if not fully deployed, just a slight polish on what is fully deployed. I think you will be able to then ... and see ... that there will be a whole lot more interoperability should you be able to either include in the reg a base implementation guide or, if not contemporaneously issue a guidance letter with the reg saying these are the implementation things we recommend.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Let me just make sure – let me read that back to you and make sure I understand what you're suggesting. That is that our recommendation in that case would be that the reg would have both, a very broad, general statement about the adopted standards as a level of, for example, of HL7 v2 period. And a minimum requirement for use of a specific implementation guide within that standard, such as the 2.5.1 ... guide.

This is really the question for the group on the phone and it's also something that the feds have to weigh in on. I would think that since these things don't change that fast and there does seem to be lack of controversy in certain domains that doing that would actually address concerns we have as a committee, concerns the HIT Policy Committee has, concerns I've heard from the industry and it's really their choice that in the reg itself we say, "Here is the implementation guide. Oh, but by the way, we know that as this implementation guide evolves additional guidance letters need to be issued," or do we leave the IFR effectively as it is. It's HL7 2.5.1 for now, oh, and a guidance letter comes out the day after the IFR

becomes law and says, "Here is a pointer to the HL7 2.5.1 implementation guide that everybody should use."

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

So talking through this, the two approaches, it's HL7 or it's HL7 2.5.1 in the regs each of those supported by an implementation guides that can be updated through guidance letters. Putting 2.5.1 in the reg assures industry that some ... can't get together and make a radical change, which has a lot of weight I think for it. The process then for dealing with technical corrections that come up in effect I guess what we're saying is the guidance letter specifies ... if we say 2.5.1 we still have to have a guidance letter that specifies an implementation profile of 2.5.1, right?

**M**

Yes, but I would say that's equally true if the reg only said version 2.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

No. I agree, so this is really a pretty – I think the discussion we're getting down to is, on the one hand, we can provide an assurance of more stability at the cost of making it very difficult to adopt a new release of HL7 v2, which will lead over time to include your implementation guidance, but if we do that then we satisfy a certain component of the public and the influencers that sort of work behind the scenes that we've created stability for the industry.

I guess what I'm most – the thing that ... frequency is I'm not sure that if you include the labs in it you can get a consensus on it. John, do you think? We never did really get closure with the labs through HITSP. Do you think that there is an implementation guide out there that the labs and everybody else in this ... can agree on?

**John Halamka – Harvard Medical School – Chief Information Officer**

I think it sounds something like this, which is on one hand labs have been reluctant to adhere to any implementation guide in that they are the significant heterogeneity in all the commercial labs of this country that would require retrofitting no matter what standard you move to –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes.

**John Halamka – Harvard Medical School – Chief Information Officer**

And two, they don't want to have optionality and things that might be needed for public health or non, what I'll call, EHR lab data exchange they would rather not bother with.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes. Let's just say things they don't get paid for.

**John Halamka – Harvard Medical School – Chief Information Officer**

Right. Sure. And so hence, an implementation guide that includes demographics, which would be wonderful for bio-surveillance or public health recording or whatever. The lab doesn't have any real desire to implement it, so I think this is one of those where we know what the requirements need to be. They are defined in meaningful use. We therefore need a standard, which supports those requirements and therefore, the lab has to be given some time to adopt, but it really can't be a choice that you –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**



Let me just ask a question. Is the argument for that so that everybody uses the same standard or is the argument for that we need to get data from the lab in order to meet the public health mandate?

**John Halamka – Harvard Medical School – Chief Information Officer**

I think the latter is the meaningful use basically says you will do public health lab reporting. You will do some ... surveillance and the only way to fulfill that is to have –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

That's what I'm not so sure of. Meaningful use does not impose any requirements on the labs except, arguably, when the hospital operates a lab perhaps it does, but as far as the independent businesses, their labs, meaningful use doesn't. The requirement is on ... living organization to report this surveillance data. One assumption is that ... placed an order for this patient. They have the demographic data.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

So, it gets back to then architecturally are we suggesting that the lab would do nothing more than receive an order, send a result and then it is up to every provider and every hospital in the country to then reformat that result to submit it for all population health perspectives and therefore the lab would never be in a population health data submitter role.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I would say just slightly different than that, which is that until there is a legal mandate for the lab to do that then there is no argument for creating a standard that causes them to ... their systems.

**John Halamka – Harvard Medical School – Chief Information Officer**

Yes. I would add a legal mandate or an economic incentive or ....

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. Right. Yes.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

As currently written, my understanding of the IFR is that there is nothing stated about an EHR receiving a lab result, having to receive it in HL7 2.5.1 format. The only HL7 2.5.1 that's stated is for the public health recording and there is no mandate that a hospital lab sends data in HL7 2.5.1 to an EHR and those I think are two gaps that if we love HL7 2.5.1 as the currency for all hospitals, all EHRs, all public health, you would think that would be a direction ....

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I've obviously sort of lost my ... a little bit here, but I'm going to argue the other way on philosophical grounds. I mean one set of philosophies says that the more you create uniformity among interfaces the easier it is to ... systems.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Right.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

The alternative one is that the more you enable the use of existing systems and reduce the implications of getting to a standard the faster you roll out the standard interfaces. The way I interpret the current schism between the NPRM and the IFR is that we only require standards ever in certification except where we have sort of a legal mandate on behalf of the receiver, which is CMS for quality measures. By the IFR and creating certification, we expect to make those standards the logical choice to get there, but not

compel them to happen in a time frame of a specific stage of meaningful use or something like that, so if you can scratch the meaningful usage with ... then that's okay.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

That's generally true except where it isn't, so as an example, the problem ... being maintained in one of the specified standards of vocabulary and so forth, right?

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. Okay. So, I think there may be exceptions, but if we just focus on live data for a minute. I would say that there is a law, not our favorite law, the HITECH Act, but there is a law that specifies a specific format for reporting lab data to public health, right? And we don't have any option to change that law. We, therefore, do imply a specific standard for whoever is required by the mandate, by that law, to report to public health. I haven't read the law, but as far as I know, it's hospitals and practices that are required to report to public health. Is that a good assumption or –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

What the meaningful use will state is that eligible professionals and hospitals have to demonstrate one transaction being sent to reportable labs and ... surveillance and immunization registries should there be a receiver capable of accepting ...

**M**

Yes, as a test.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

... test.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

There is a production requirement yet.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

And in the IFR, of course, it says and when you do that test you can choose 2.3.1 or 2.5.1 and you can use the ... vocabulary for immunizations.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Does the IFR say that or does it say your software has to be certified to use one of those formats?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes. The IFR says your software has to be certified to do that. It's the NPRM that says that you have to press it once basically.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right. So I guess it may be that for public health there is a reasonable assumption that the NPRM requires the use of a specific standard because there is another law that requires the use of that

standard. If you're going to submit to public health this other law says you've got to use the standard, right, the Public Health Act?

**M**

When you are saying law, I mean ARRA and HITECH don't specify the need to do public health transactions. NPRM states you need to do a test and IFR says you certify your EHR using ... for that.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. The reason I'm stumbling on this is that what I recall, and I can't find the language right now, is that that section of the IFR states that the standard for submission to public health is defined in the Public Health Act rather than through the HITECH Act.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, I mean that's the act that includes HIPAA, so that's where the HIPAA standards are. I don't know that there's an actual public health reporting –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

All right. So I may be confusing the issue here then. I'm sorry.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes. I mean I think that's true for the HIPAA transactions. I think for public health it's up to the local public health agency or ... requirement and to what particular message format.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

So what happens right now? Do, in fact, reference labs submit directly to public health? If you –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Not generally. I mean I think it's highly variable but generally not.

**M**

So, for example, I am submitting to public health and to CDC 4,000 data elements today, but I am unaware of Quest or LabCorp doing so. Of course, one wonders with the H1N1 epidemic how was it these cases were identified. Was it ... reporting by providers and hospitals or was there – I just don't know the answer to this.

(Overlapping voices.)

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I think a large majority of the public health agencies don't have a lot of capability to receive or are they receiving a lot of electronic reports?

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

My view is ... telephone, but let's— What we understand is there's a stage one requirement to test, if you can find somebody to test, sending to public health and there is a certification requirement for a certain standard for sending information to public health. We have a lot of reason to believe that in the stage two requirement may require you to put that test into operation. We certainly would like to see that happen without changing the spec that you're required to use for it and there is a fundamental, business driven dissidence between the spec for public health and the spec that the labs would like to have for reporting data to EHRs.

**M**

That's true where the public health did a few more data elements. Basically they message this universally reusable for all ... and clinical –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes, and while it is just a handful of data elements, as John said. It's also true that these are not data that are ... in a lot of laboratory information systems that aren't used for that purpose today, so it would require a substantial change.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes.

**M**

So then for our recommendations to the committee next week, I mean it seems to me like we're down to do we want to suggest that the IFR itself includes implementation guidance, which conceivably, for labs could be different for the public health and the EHR? Actually, it says nothing about the EHR. Do we even want to tell them you should say something about the EHR or the hospital? That's one set of questions. Do we want to have guidance letters issued separate from the IFR?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I was going to say it seems like we're going back to some previous parts of the conversation. It seems like we're talking about two things. I wanted to try to frame them both together. One is the idea of broad standards in the regulation with specifics that would be issued in advice letters or guidance letters or some other mechanism or in certification criteria that could change annually or maybe it's ...all of those things.

So in terms of broad guidance we are talking about the possibility of moving from a particular version of HL7 v2 and a particular version of the Version 3 CDA to broaden that to be potentially any version 2 and any version 3 in a regulation and then have certification and advice and guidance give the particular implementation guides. So, that's sort of one part of the conversation.

The other part of the conversation has been about what is the minimum or is there a minimum required implementation guide, which should be specified in the regulations in addition to the things that would change over time so that there's at least a baseline for a specific implementation guide. So is there any inconsistency, I'll say, or maybe is there any disagreement that, in the first place, we want to have generally a broad standard in the reg and then have mechanism for updating implementation guidance more rapidly? I mean that's the general framework and it seems like there's agreement to that but let me just–

**John Halamka – Harvard Medical School – Chief Information Officer**

So basically what you're suggesting maybe the reason there's so much push back from a variety of stakeholders ... they just didn't really understand ... the intent and if we state the intent is that we want to give you very specific implementation guidance, but there is worry about a reg being cast in concrete. So what we're going to do is in the reg we're going to state here is a broad class of standards that's concurrent with the issue ... the reg we will have guidance letters and certification ... a specific implementation guide that gives us the flexibility to evolve over time. That all seems like it hangs together.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I think conceptually, yes. Given you have ... ear to the ground than most of us do, John, what do you see the push back that you're hearing now? Is it that the reg is not specific enough or that it's too specific?

**John Halamka – Harvard Medical School – Chief Information Officer**

Well again, it depends on your domain. In the lab domain saying HL7 2.5.1 is as equivalent to saying build a railroad between Boston and New York. I'm not going to tell you how wide the tracks are.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right.

**John Halamka – Harvard Medical School – Chief Information Officer**

It's interesting and you'll get a railroad just have to change lines 17 times because it's implemented different ways.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right.

**John Halamka – Harvard Medical School – Chief Information Officer**

... and so I think there are many who would rather just be told these are the fields. This is the optionality. These are the code ... and something ... more implementable with interoperability.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

So the pushback is towards specificity at this point?

**John Halamka – Harvard Medical School – Chief Information Officer**

On the lab, and again, I haven't heard from anybody in a reference lab world recently, but what I hear on the software vendor side and on the provider side is it would be so much easier rather than doing one off custom lab interfaces with custom ... to just say, "Here is the 99% ... test compendium vocabulary. Here is the single implementation guide for lab." Do it once and you're good.

**M**

And that's the minimum requirement.

**John Halamka – Harvard Medical School – Chief Information Officer**

And that's – yes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

All right. So it looks like we have within the framework of the two regulations, the proposed and the interim, we have the ability to suggest what should be certified is not what should be done operationally and we have the question that remains is it in the interest of the country to have a different specification for public health lab reporting or to have the same one where the differences if they're different are modest.

**John Halamka – Harvard Medical School – Chief Information Officer**

And also related to that is there is no specification currently for the EHR receiving the data or a hospital serving as a reference lab and .... Jaime, based on your experience, what do you think in terms of having a different implementation guide for public health reporting and for EHR lab exchange? Should ONC specify in stage one that EHRs need to use that specification, whatever it is?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, I mean I guess from my standpoint every time there is a different spec for ambulatory or hospital providers to use in reporting to public health or for surveillance purposes versus the ... spec that's used for resulting to the EHR then it's just 100% more work every time there's a change.

**John Halamka – Harvard Medical School – Chief Information Officer**

I agree.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

So if there were basically one message spec that could be used for all three purposes then you would cut the amount of work by two-thirds for all of the providers in the country.

**John Halamka – Harvard Medical School – Chief Information Officer**

That would be my opinion as well and the counter argument that Wes gives is is it better to get HL7 messages flowing even if they are variations –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

With standard compendium.

**John Halamka – Harvard Medical School – Chief Information Officer**

Yes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right.

**John Halamka – Harvard Medical School – Chief Information Officer**

Because they already are implemented or do we push the country to 2.5.1 and every time therefore after we move to 2.6, 2.7, 2.8, we're moving all three interfaces concurrently?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I think this goes back to the cost benefit argument in terms of the economic value of the incentives as well. If this is one of the things that's going to multiply the cost I think it needs to be considered ... –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I'm going to argue a little bit with what Jamie said. Every time you build an interface it involves a complete testing cycle. Generally when the interfaces are highly similar, it's ... you have some way to count on the continuity of that similarity. In other words, it's not just an accident of this week that they look similar. Then the development and engineering costs are substantially lower. I am not aware of a lot of institutions that save incoming lab messages as data as opposed to posting it against the repository and therefore, I have been assuming that it's not much programming work to add the data elements that we're already keeping to create a message, send it out through an interface that was built using common tools, but has slightly different specifications for what data elements you're poking into the message.

**John Halamka – Harvard Medical School – Chief Information Officer**

Right, I mean so for us to go from 2.3.1 to 2.5.1 is quite straightforward, right, because we use integration engines and we're going from a repository to an integration engine and ...–

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right.

**John Halamka – Harvard Medical School – Chief Information Officer**

Or–

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Or another facility might say an EHR, which has a repository sort of built in under the covers, but it's the patient data.

**John Halamka – Harvard Medical School – Chief Information Officer**

And similarly, parsing in 2.3.1 versus a 2.5.1 message in our integration engine is no real problem, but as Jamie pointed out, the issue with the lab is ... the lab has no capacity to store in a repository patient demographic information. So, an order comes in, they can't store it and now they have to send it back out, but it hasn't been stored to begin with.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. That's a different case. I mean we have a case where there is data that is not collected that's required in an outbound interface and that is always going to be a high impact, because now you're going to have to start getting it on your inbound interface. You're going to have to change your screens to collect it for walk-ins. I mean it just turns into a major, major piece of work, so I would regard that as a different analysis. So I would be saying that given that the only requirement we see is stage one or stage two is, for this information to go to public health from a care delivery organization, given that it would be extremely expensive for the labs to add that data to give it to the care delivery organization so that the care delivery organization can give it to public health and ... care delivery organization already has the data anyway then I would argue that it's well justified in having two separate specifications for delivering lab data and we can help the industry a great deal by making them as similar as possible, as long as they're each responsive to the business needs of their use case.

**John Halamka – Harvard Medical School – Chief Information Officer**

Jamie, unfortunately, I have to jump to another call, but I would say that in general I am very comfortable with the idea of having the IFR provide a general standard and a ... and guidance letters and certification to be issued with further detail in support of that ....

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

All right. So the implication is, as an example, that the reg might say version 2 and a minimum and have a certification requirement for 2.5.1 for a particular implementation guide. Is that the right direction or would you put the particular lab implementation guide in the reg?

**John Halamka – Harvard Medical School – Chief Information Officer**

And, again, I think what we're hearing from ONC, as I mentioned, was two things. One, their ... fear was the second you get implementation guides in a reg it's very hard to change and even though you think you could say, "Here is the floor ... will go up from there," the regulations aren't built that way. So I think we just need more guidance on that.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes.

**John Halamka – Harvard Medical School – Chief Information Officer**

And that the fear also is that we better be sure that the implementation guides we are suggesting are widely adopted and loved in the industry because otherwise we'll be imposing bleeding edge technology on small providers, who can't afford it.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. I would suggest we record a comment that there is a circularity associated with widely adopted and there is a need for small point corrections to happen more rapidly than major changes.

**John Halamka – Harvard Medical School – Chief Information Officer**

And to the point that was also made is there's a difference between imposing an IHE profile on someone when that has only been demonstrated in ... versus you're already using 2.3.1. We're going to 2.5.1. It's not a big deal really.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. I think we're, at least the three of us, are in accord on that.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I think so.

**John Halamka – Harvard Medical School – Chief Information Officer**

Well Jamie, I will follow up via e-mail. I think we are very much headed in the right direction. It will be a great discussion next week.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay. John, thank you very much. John Klimek and Eric and Chris, I haven't heard much from you. I'm wondering how you feel about this general direction that we've been discussing of perhaps broadening or making a recommendation for broadening the regulation but adding specific implementation guidance.

**Chris Brancato – Deloitte – Manager, Health Information Technology**

This is Chris Brancato. I guess some of those things I was reacting to is what Wes put on the table, so I want to say a couple of things. Wes, some of the questions that you posed hopefully there will be answers in the forthcoming certification and DRM. You may not like them, but I think some of the questions that you asked will get answered in terms of standards to certification criteria.

The other thing I was thinking about is so I'm a system implementer and I look at my series of product offerings out in the world and then I ... have to consider. So what are the things that drive me to want to see a revision to the software based on the standards? The first one of those is there is obviously an error in the original standard that causes the interface to be unstable or the data to be unreliable. And the second part of that is there is a gap of functionality that the customer needs. So, I'm sitting here pondering those things and wondering about so how do I manage those things into a regulatory cycle with the recognition that some of the updates that come out in ... or addendum to the standards happen between regulatory cycles and can be pretty profound as far as the software .... Those are my thoughts, at least the ones I wrote down.

I would add, going back to the previous conversation, we identified one implementation guide for HL7 v2 that has not changed, but then just I'll point to a different example in terms of implementation guidance for the C32 specification of CCD, which has changed and where there are, and I can say for our own part we're in the process of upgrading from 2.1 to 2.5 for particular production exchanges that we have going on and those are your material software changes. That's a more frequent update process.

The other thing I want to kind of ponder and look for yours and Wes's feedback is the notion that let's say I want to use an implementation guide that's out there in the world and that implementation guide essentially looks like HITSP IS or FC or and IHE construct. So the Standards Committee recommends standards for adoption for the national coordinator to consider. So what do you do with those implementation guides that include standards that are not specified?



**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I hear you, but I think that may be one of these buckets that we actually want to talk about because, in fact, the same thing is happening in terms of some of the quality reporting where there are standards that are required for calculation of some of the quality measures that were not adopted.

(Overlapping voices.)

**M**

... we'll need some guidance on that.

**John Klimek – NCPDP – VP Industry Information Technology**

Jamie, this is John Klimek. In listening to all of the conversations that have been taking place in the last hour and listening to some of the guidance that's come out, I'm in full agreement that ... towards some implementation guides helps move towards interoperability. I only can relate to that in the pharmacy world with us moving to different standards ... what was previously discussed. The only reason why pharmacies move to other versions or newer versions is because of business needs. Our members come to us and they have certain requirements or needs because of different types of functionalities that are happening because of rules and regs and laws and new types of needs out there, so business needs are definitely a high priority. Then also, there are those gaps in functionality, but pharmacy in the past and in the future has always been on top of the game as far as moving towards newer and faster and quicker and better versions.

I'm sort of struggling with listening to some of the complaints and concerns about moving to versions and labs not willing to cooperate with any type of a standard out there. It sort of bewilders me from our standpoint of how we've dealt with ... in the past.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I think it would be an exaggeration to say that the labs aren't willing to cooperate with any standard out there. I think that what happened was that ... got the labs started in a group defining a standard, a variation of HL7 v2, got HITSP started defining a variation of HL7 v2 with a broader mandate in terms of number of use case it had to cover and when the two came together we were never able to reconcile them. In the labs, not having any lever, ended up saying, "We'll just do what we're doing." I mean not that they're not willing to adopt standard. They felt that the standard that HITSP was coming up with was onerous and there was no lever to get them to adopt it. As it came out of the discussion today, and I hadn't realized this before, it sounds like they had a pretty solid business reason for that position.

**John Klimek – NCPDP – VP Industry Information Technology**

Well, and again, I didn't mean to say that they didn't want to move towards the standards. Obviously, they probably had some business needs to do that, but I guess and not trying to come up with a consensus. I keep going back to our methodology of developing standards in a consensus process and everybody buys into the process, whatever that implementation is set for that standard, that's pretty much governed by the business needs.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst** So what we have with labs but we don't have – I'm assuming you're talking about ..., John?

**John Klimek – NCPDP – VP Industry Information Technology**

Yes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes, is a convening point that created a consensus. They created a voted on document, but the result of that did not represent a consensus of all of the stakeholders in the room. I think there are business reasons about the variance in scope between ... a whole bunch of reasons why it didn't happen, not the least of which was some really unreasonable deadlines that HITSP was working under. But I would say that we certainly need to do better, but we certainly have to recognize that the consensus has to represent, it has to not be – the problem we have is that everybody tends to defend things for trivial reasons and you have a hard time knowing when you're defending things for important reasons –

**John Klimek – NCPDP – VP Industry Information Technology**

Right. Exactly.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

If you know what I mean.

**John Klimek – NCPDP – VP Industry Information Technology**

I know exactly what you mean.

**Chris Brancato – Deloitte – Manager, Health Information Technology**

Jamie, this is Chris. One last comment is we're talking about making recommendations to regulation in terms of iterative versions of standards for vocabularies. The reality of it all is if I were back in private sector running a software company I would sit there and really consider with my product releases whether I go from 2.3.1 to a version ... 2.5.1. So they don't necessarily have to be iterative in that respect. We might want to consider gap jumping –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

No. I think, Chris, that's an argument that supports the recommendation to broaden the regulation to HL7 v2 period and then provide guidance that may jump the versions from 2.5.1 to 2.7, for example.

Let me bring up one other thing in the same general trend. So, we've been talking a lot about version 2 messaging, but there are also version 3 standards, HL7 v3 standards that are adopted, specifically, the clinical document architecture release or I guess level two – release two, level two. The others feel that it would also be good to broaden that to a general statement about HL7 v3 with again specific implementation guidance for the particular CDAs that are needed. I don't know if there is a family also that CCR fits into, but I would say that same thing on the CCR side.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

If you could repeat that, Jamie; I got a little bit distracted.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, the question is about HL7 v3. I think we have consensus that it might be a good idea to broaden the reg to HL7 v2 and then provide implementation guidance ... for the particular purposes of 2.3.1, 2.5.1 and potentially jumping versions when that's appropriate in guidance and certification and other mechanisms. But I was noting that there are some v3 standards that have been adopted, which is CDA, and I wonder if the same thing is true for broadening on the v3 side to either say CDA period or v3 period even. And then provide implementation guidance for the specific CCE Version 2.5.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I think the important principle is that no interoperability will be achieved without an implementation guide and as a result the purpose and, in fact, mentioning implementation guides in the reg creates inertia in terms

of changes that is often ... the difference in getting it done may be measured in years. So ... we recommend as an approach that the specification, the regulation be ... enough to identify a family of standards and you want conservatism about that, but leave the implementation guide based on that family of standards to a specific action in terms of guidance letters.

I'm sorry for going back over old ground here, but I'm just trying to fit this in. So the question arises what is the level that is appropriate for recommendation in the regulations for requirements in the regulation. I think that the answer there is very specific to the topic. For example, HL7 v2 is probably the right one for HL for lab messages and you certainly wouldn't say HL7 v3, because that includes the CDA and version 3 messaging, but I would say the clinical document architecture for the specified requirements.

As far as for CCR, I am not aware that there is anything except this specific AFC and CCR recommendation. I don't believe it's part of an architecture.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I think that's my understanding as well. I just wanted to ....

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes, but I would want to get that from somebody from the ... rather than be accused of .... And, as far as ... let's get the guidance from them.

**John Klimek – NCPDP – VP Industry Information Technology**

John Klimek. I mean I think it would just be scripts in that meaning, which would then allow implementation guidance to provide the update for version. Is that right?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, maybe we lost him, but I think we could validate that, but I think that would be the case. Actually, there were not specific versions in general of the adopted vocabulary that were specified, so SNOMED ... didn't really a particular release ... adopted in IFR, so that would be inconsistent. It's already done in that case.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes, I would say right with the understanding that even for HIPAA, they had a lighter weight process for adopting new releases of vocabularies than they did for new releases of a transaction ... and that has to continue because that's just the nature of compendium.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay. There's one other area that I want to go back to the original sort of list of buckets. There is one area that I forgot to mention and that is that we had talked about previously. I did want to bring it up here and that's another area of inconsistency, so we might have an inconsistency bucket where there are potentially some with HIPAA, some between the IFR and the NPRM. But this one is inconsistencies with other federal requirements that are federal contractor requirements and subregulatory requirements in the CMS call letters that under the executive order 13-4-10, contractors and CMS Part C and Part D call letters require the use of recognized standards, which are the HITSP specifications. So that's a much greater level of specificity that could potentially conflict with these requirements. That's an inconsistency that we had noted on a previous call we wanted to find out as well. I'm not sure if we want to recommend a resolution of that or not.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I would say that I understand that particular executive order and those call letters as being a bit of a paper target right now –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

No, I'm not saying there is an enforcement, but I still believe there is a compliance requirement with the ....

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. I think we should recommend we could identify the issue of the inconsistency and recommend that the principles that the ONC is applying for identifying standards would be appropriate for identifying standards on the executive order. So we're sort of hinting at ONC take this over, but we're not saying it per se.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

But not recommend a particular method of resolving it?

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. I think lay men advising the government on how to deal with the government is like telling your surgeon how you think he ought to operate.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Right. Right. Okay. What other or are there more on this topic or other topics –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I hate to be always the one with his hand up, but several times now, in several discussions we've talked about CDA level two and level three and to two points. One is you say that level two allows nothing but texts. Level three requires coding. It's my understanding that level two is sort of a broad characterization, but releases are the specific way you identify CDA standards, right?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Right. I think that it gets to the usage of the standard within the release level.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right. I don't know. Level two was originally the basis for progression of the CDA architecture and it was, at one point, just abandoned for the use of releases instead. I don't know whether level two is just a metaphoric statement now or whether it's precisely defined.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I don't know either. But, one of the things I was thinking in getting back to the ... attachments in NPRM is that they had a particular way of characterizing level two and level three there as the human readable and machine readable variants. I wonder if we would want to recommend that that way of expressing the way to use CDA should also be adopted here.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Well, I think they have addressed that issue through language that talks about the distinction. Actually, that's an area that could really use some qualification, some clarification. Unfortunately, I can't find it right now ..., but fundamentally they are addressing that issue through language that I think is pretty ambiguous and we might want to include a statement about that, but I would have to go off-line and find that and send it out to –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Well, what we could do is we could perhaps adopt some of the language from the ... attachments NPRM just in requesting clarification and just say that we would request verification on the use of structured and coded data and machine readable documents versus human readable ....

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Yes. I think we need to, one, look for clarification; and second, look for, as best we understand it do we agree with their approach or not.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

One is just to request clarification, but then I think what I was suggesting from our previous conversation was that we should actually have a recommendation that level three where a machine readable document should be a requirement in addition to a human readable.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

I think that for certification that's ... true.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Right. That's what I was ... my comment, yes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Okay. All right. I think they're trying to stay with their philosophy of taking one foot on a pier and one foot on a boat with CCR and CCD. What I believe that they should have said or they intended to say was that you need to receive the documents in both formats and be able to display both formats as human readable content and you need to be able to accept one of the formats and ingest the structured data and save it in your database as structured data rather than as text. But I think that the way it's written right now it almost says you've got to be able to receive it and print it, but you don't have to save it. Retrieve it and ... save it.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I think that's the way I read it too, yes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Right and I don't think that's appropriate.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Right. Chris, any comments on that one?

**Chris Brancato – Deloitte – Manager, Health Information Technology**

No, I don't have anything to add to that, Jamie. Thank you.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay. Wes, anything else on your list?

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

No. I really appreciate all of the work just keeping a list. If I kept a list of all of the things I commented on to someone I'd be ... more organized.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I've got about five pages of notes on this, but I'm trying to condense it down to just a few slides with sort of large typing –

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

You know exactly the language I was referring to so you know how to prepare a comment. Okay. Great.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Exactly. Then what I will do is at the same time as I'm finalizing these slides for next week, I'm going to draft up some possible comment language and suggest and I'll have that available as well.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Okay. So I would say we had a pretty good, active session. Are you just moving on to another topic here?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

No. I just wanted to ask and make sure that from any of the participants here that there weren't any other subjects to bring up or any other comments on the things we've discussed at all and then I think when we're done with that part I think we're ready for public comment.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Jamie, just one question regarding the slides, you will be able to get them to me by Monday do you think?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Yes.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Oh, good. Okay.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

I've got them in draft right now. I just need to format them for you.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Yes. I've gotten Dixie's material already. I might send that out to you all as soon as I get off this call.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay. Great. Okay.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Are we ready for the public do you think?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Let me just check. I heard Chris, John, Wes. Anything else for this call?

**Eric Strom – DoD Military Health System – Program Management Support** Nothing from Eric.

**Chris Brancato – Deloitte – Manager, Health Information Technology**

Nothing from Chris.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Okay. Latanya, if we can ask if there are any comments or questions from the public.

**Moderator**

There are no public comments at this time.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Okay. Thank you. Thank you, Jamie and everybody.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Let's wait just a minute and see if anybody dials in just to make sure.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Okay. That was a very comprehensive call.

**M**

Yes it was.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

I always like to think I'm continuing my graduate education here.

**M**

Well, we usually have to choose between comprehensive and comprehensible, right?

**Judy Sparrow – Office of the National Coordinator – Executive Director**

I think you hit both. Even I understood it.

**M**

Oh, gosh.

**Judy Sparrow – Office of the National Coordinator – Executive Director**

Oh, gosh is right.

**M**

We're going to all lose our jobs if everybody else gets to understand what we're doing.

**Moderator**

We don't have any more public comments.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Okay. Folks, thank you very much for participating today. I really truly appreciate it and look forward to seeing you all next week.

**Participants**

Thank you, Jamie. Good-bye.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**

Thank you. Good-bye.